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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/608,408

06/27/2003

Brian R. Will

WILB01

8452

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

07/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/608,408

Applicant(s)

WILL, BRIAN R.

Examiner

david shay

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 18, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 16, 2008 has been entered.

Applicant has sworn an affidavit under 37 C.F.R. 1.132, which will be analyzed here. Affiant first states, after noting that the Affidavit is in response to the office action of April 11, 2007, that affiant reiterates the statements and arguments made in the previous affidavit under 37 C.F.R. 1.132, executed January 10, 2007. This is noted, and the examiner's responses and rebuttals of the arguments made therein, as more fully set forth in the office action mailed April 11, 2007, are hereby incorporated by reference herein in response.

In paragraph 3, affiant states, that affiant is a board certified Ophthalmologist with 17 years experience; has performed thousands of surgeries; and is familiar with devices such as those in the applied art. It is also noted that affiant makes reference to the experience of others, who are not signatories to the affidavit. As such, the opinions of these others are of little moment.

Affiant then asserts, in paragraph 4, that affiant and staff members meet regularly to discuss patient outcomes. And in paragraph 5 asserts that the examiner has expressed skepticism that prior art devices using annular vacuum rings "such as described in Hellenkamp" cause complications in patients undergoing LASIK. Affiant also noted that the descriptions are not speculative, but are the subject of growing concern.

The examiner has already pointed out that the description affiant has put forth regarding annular vacuum rings “such as described in Hellenkamp” appear to be addressing devices of the type illustrated in Figure 1 of Hellenkamp. Affiant has not denied this assertion. The examiner respectfully requests that affiant clarify by explicit statement that the statements sworn to with regard to experience in the field with, and problems observed from the use of a fixation ring of the type illustrated in Figures 4 and 5 of Hellenkamp in order to clarify the issues and forward the prosecution of the instant application. Until that time, Affiant’s continued vagueness on this point, absent a contradiction of the examiners clearly stated assumption, must be construed as indicating that the examiner’s assumption is correct: that Affiant is addressing the use of suction rings of the type illustrated in Figures 1 and 2 of Hellenkamp in the instant (and prior) Affidavit.

In paragraph 6, Affiant discusses the Article attached as exhibit 1, noting that the conclusion of this article is that high vacuum settings can cause problems in posterior structures. While this information is interesting, it is immaterial to the claimed invention, which nowhere recites a vacuum source, let alone particular settings thereof. The issue regarding the precise nature of the suction rings “based on Hellenkamp” is also a problem here.

In paragraph 7, Affiant discusses the article attached as exhibit 2, which again deals with harm to the eye caused by the application of vacuum using suction rings. Again, while this information is interesting, it is immaterial to the claimed invention, which nowhere recites a vacuum source, let alone particular settings thereof.

In paragraph 8, Affiant discusses the article attached as exhibit 3, which again deals with harm to the eye caused by the application of vacuum using suction rings. Again, while this information is interesting, it is immaterial to the claimed invention, which nowhere recites a

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vacuum source, let alone particular settings thereof. Affiant expresses the “belief” that the displacement of the sclera into the high chamber of the suction ring is the problem. There is no addressing the fact that the insert of Hellenkamp, as illustrated in Figure 4 thereof, which clearly reduces the height to which the sclera can be drawn (by virtue of taking up some of the space in the suction ring), may also alleviate this problem, nor is there any discussion whatsoever of the membrane of L’Esperance, which would clearly prevent the scleral displacement asserted as the cause of the problem.

In paragraph 9, Affiant discusses the article attached as exhibit 4, which again deals with harm to the eye caused by the application of vacuum using suction rings. Again, while this information is interesting, it is immaterial to the claimed invention, which nowhere recites a vacuum source, let alone particular settings thereof.

In paragraph 10, Affiant discusses the article attached as exhibit 5, which again deals with harm to the eye caused by the application of vacuum using suction rings. Again, while this information is interesting, it is immaterial to the claimed invention, which nowhere recites a vacuum source, let alone particular settings thereof.

In paragraph 11, Affiant discusses the article attached as exhibit 6, which again deals with harm to the eye caused by the application of vacuum using suction rings. Again, while this information is interesting, it is immaterial to the claimed invention, which nowhere recites a vacuum source, let alone particular settings thereof.

In paragraph 12, Affiant asserts that the attached exhibits “as a whole demonstrate that the existing industry suction rings, which are essentially versions of the Hellenkamp and Curtin/Clark, are known to be problematic in LASIK procedures” (emphasis added). This

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assertion is simple speculation (albeit not without evidence), regarding the source of the problem, and still does not address the exact ring design disclosed by Hellenkamp, as already stated above. Further, this completely ignores the teachings of L'Esperance, as discussed previously.

In paragraph 13, Affiant discusses the L'Esperance suction ring. Affiant asserts the opinion that such a device would not work. However, there are no tests or other evidence on which this assertion is based. Apparently the small holes of Affiant's device do not have this problem, what if the membrane of L'Esperance were designed to have an average pore size near that of the holes of the instant device, which are apparently immune to this deficiency.

In paragraph 14 Affiant addresses the examiner's perceived "skepticism" regarding "high profile" as contrasted with "low profile" suction rings.. The examiner has not intended to indicate skepticism, so much as confusion. The term "low profile" appears only twice in the originally filed disclosure, and there is no real definition associated therewith. As such the portion of the membrane of L'Esperance that protrudes beyond the border of the metallic portion of the suction ring, could be considered a "low profile" portion of that suction ring. Further, as there is not real definition of this term set forth, the ring of Hellenkamp, which according to the illustration thereof rests low down on the eye, could be considered "low profile". Essentially, the disclosure was drafted with little emphasis or description of this feature. Attempts to base patentability on a structure so treated are generally problematic, as exactly what they are and what does not fall under the definition of such minimally mentioned structures is open to much debate.

In paragraph 15, Affiant discusses the utility of “low profile” suction rings, asserting that the “low profile” is achieved via the criss-cross channels. While whatever is encompassed by the term “low profile” suction rings may have such advantages, it is not clear that the rings of the prior art do not fall into this category..

In paragraph 16, Affiant describes hypothetical problems which are theorized to occur with the prior art rings. As there is no evidence per se regarding such problems, their complications, or their resolutions, this paragraph is merely conclusory.

In paragraph 17, Affiant discusses the articles attached as exhibits 1-6, which again deals with harm to the eye caused by the application of vacuum using suction rings. Again, while this information is interesting, it is immaterial to the claimed invention, which nowhere recites a vacuum source, let alone particular settings thereof.

In paragraph 18, Affiant asserts that the instant device “teaches an opposite approach – to improve accuracy of flap cuts and corneal shaping by minimizing vacuum fixation and flap cutting portion of the procedure”. However, as the originally filed disclosure makes no mention whatsoever of flaps, this assertion is not convincing.

Turning to the remarks, applicant asserts that convex and concave can mean the same thing. This is not convincing, as the terms are antonyms, and applicant has provided no definition in the originally filed disclosure to assert that the terms should be construed with their opposite meanings.

Applicant argues that “clearly applicant is not claiming that the entire device fits under the patient’s eyelid”. The examiner must respectfully disagree. It is far from clear what is meant by this term. It is only mentioned in the originally filed disclosure twice and in neither case is

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any particular portion of the device recited as having this property, the entire suction ring is referred to as "low profile". Thus this argument is not convincing.

With regard to the art rejections, applicant argues that the examiner has not provided motivation to combine the references. The examiner must respectfully disagree. Motivation is clearly provided at the last sentence of the rejection. Applicant requests an affidavit regarding the official notice. Is the examiner to understand the applicant, an accomplished eye surgeon with 17 years experience and thousands of LASIK procedures, is unaware of the fact that, and requesting official notice for the fact that centrality of the suction ring is critical to the proper outcome of a LASIK procedure? If so, the examiner so swears.

With regard to the use of single references under 35 U.S.C. 103(a), the examiner notes that the originally filed disclosure specifically states that "criss-crossing channels 16 can be configured in many different ways to create a substantially uniform pressure differential across the contact portion 14 in relation to the eye globe...so long as the configuration allows the pressure differential to be spread substantially uniform across the contact portion in relation to the eye globe." (sic). Thus clearly, the exact configuration of the channels is not critical, this fact is expressly asserted in the originally filed disclosure. In such a case, it is not incumbent upon the examiner to provide further evidence of the non criticality of this feature, as it is expressly set forth in the originally filed disclosure.

With regard to the various affidavits, the experience of the staff of Affiant is not at issue. It is the agreement with the statements of non-signatories, who, for the record, are not even averred by affiant to have even read, let alone concurred with such opinions.

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With regard to the vacuum ring of Hellenkamp, and exactly which ring is being referred to in the affidavit, it is curious that applicant's representative would go to such lengths to assure the examiner that it is the inventive ring of Hellenkamp that is referred to in the various Affidavits, while neither of the Affidavits themselves make any reference to any particular version of the ring which is being referred to. Thus until such time as a]Affiant sees fit to expressly state on the record that rings with the pressure equalizing insert of Hellenkamp are routinely used and subject to the problems discussed in the affidavit, arguments by counsel alone are not convincing.

With regard to the structures of L'Esperance and Hellenkamp including a "vacuum annulus" the examiner notes that the defining the space above the membrane of L'Esperance as the "vacuum annulus" does not coincide with the problem of having the scleral tissue drawn thereinto, as this would be prevented by the membrane. With regard to Hellenkamp, as set forth above, the insert of Hellenkamp would clearly reduce the amount of deformation that occurs.

The remainder of applicant's arguments are drawn to aspects of the instant Affidavit which have been addressed above. These arguments are not convincing for the reasons set forth above.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine the claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “convex” in the claims is apparently used by the claim to mean “having a surface which is somehow configured to be inwardly directed”, while the accepted meaning is “curved or rounded like the exterior of a sphere or circle”. The term is indefinite because the specification does not clearly redefine this term. Similarly the term “low profile” as used in claim 22 is indefinite, as it’s meaning is unclear. While the drawings purport to show a “low profile” device, the cross-section shown in Figure 4 clearly shows a device, the total height of which is greater than one half the diametric extent thereof. This cross section does not show either the X- or Y-translation members, which add substantially to the total height of the device. It is unclear how such a device can “fit comfortably under the eyelid”. Claim 22 is also indefinite because the exact meaning of the term “the profile of the eye fixation portion is substantially narrow” is unclear, this term lacks positive antecedent basis in the originally filed disclosure.

Claims 1, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over L’Esperance (EP ’127) or Hellenkamp. Both L’Esperance (EP ’127) and Hellenkamp teach a device and method as claimed except for the criss-cross passages. It would have been obvious to

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the artisan or ordinary skill to employ criss-cross channels in the devices and methods of L'Esperance (EP '127) or Hellenkamp, since this is another configuration that would serve to distribute the vacuum force and thus provides no unexpected result, and to discontinue the vacuum and reposition the apparatus if it is not centered on the cornea, since proper positioning of the corneal flap is critical for refractive surgery, official notice of which is hereby taken, thus producing a device and method such as claimed.

Claims 2 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp as applied to claims 1, 11, and 12 above, and further in combination with Curtin. Curtin teaches the use of adjustment arms on eye fixation devices. It would have been obvious to the artisan of ordinary skill to employ adjustment arms on the devices of L'Esperance (EP '127) or Hellenkamp, since these can be used to adjustably position the device, which is necessary due to the fact that eyes of different individuals will be in different relative locations, thus producing a device and method such as claimed.

Claims 3/1, 3/2, 4/3/1, 4/3/2, 7/4/3/1, 7/4/3/2, 8/7/4/3/1, 8/7/4/3/2, 14-16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp as applied to claims 1, 11, and 12 above, and further in combination with Curtin and Clark et al. Curtin teaches the use of translation rods and adjustment knobs to allow the adjustment in 3 dimensions of an ophthalmic surgical instrument. Clark et al teach employing X- and Y-axis adjustment mechanisms on eye fixation devices. It would have been obvious to the artisan of ordinary skill to employ the X- and Y-axis adjustment mechanisms on the devices of L'Esperance (EP '127) or Hellenkamp, since these can be used to position the device, or alternatively to employ the modified tissue/vacuum interface of L'Esperance (EP '127) or

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Hellenkamp in the device of Clark et al, since Clark et al provide no details of this aspect of the device, and in either case to provide the adjustment knob and rod configurations disclosed by Curtin, since Clark provides no details of the manner in which the translational adjustment is effected, thus producing a device and method such as claimed.

Claims 5/3/1, 5/3/2, 6/4/3/1, 6/4/3/2, 9/7/4/3/1, 9/7/4/3/2, 10/8/7/4/3/1, 10/8/7/4/3/2, 17, and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over L'Esperance (EP '127) or Hellenkamp in combination with Curtin and Clark et al, as applied to claims 3/1, 3/2, 4/3/1, 4/3/2, 7/4/3/1, 7/4/3/2, 8/7/4/3/1, 8/7/4/3/2, 14-16, 18, and 19 above, and further in combination with Olson et al. Olson et al teach the old and well known mechanical expedient of employing set screws to hold two elements in a fixed relation to each other while performing corneal surgery. It would have been obvious to the artisan of ordinary skill to employ docking screws, since these allow the fixation of devices in the adjustment mechanisms, of the combined devices and methods of L'Esperance (EP '127) or Hellenkamp in combination with Curtin and Clark et al, since these can be used to fix the devices, relative to each other during corneal surgery, as taught by Olson et al, thus producing a device and method such as claimed.

Applicant's arguments filed April 16, 2008 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and

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Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/
Primary Examiner, Art Unit 3735